

REMARKS/ARGUMENTS

Claims 1- 57 stand rejected. In the present Amendment, all of the pending claims (i.e., claims 1-27 and 29-57) have been canceled. As applicants have previously advised the Examiner, there was never a claim 28 in the present patent application. New claims 58-113 have been added. No new matter has been introduced into the present application by the addition of the new claims. Reconsideration of the present application is respectfully requested in view of the following remarks.

The rejection of claims 1-16, 18-36, 38-57 under 35 U.S.C. 112, first paragraph, is respectfully traversed. However, it is respectfully submitted that this rejection has been rendered moot by the addition of the new claims.

The rejection of claims 1-9, 11-16, 18-27, 29, 31-36, 38-41, 44-45, 49-51 under 35 U.S.C. 103(a) as being unpatentable over M.V.I.-12 package insert in view of Lundberg is respectfully traversed for the reasons set forth below.

Initially, it is respectfully submitted that there is no evidence that the M.V.I.-12 package insert was published prior to the filing date of the present patent application, which was August 3, 2001. The Examiner has relied on the date printed on the insert, which indicates that the information on the insert was revised in November 2000. The "revision date" on the insert is not evidence of a publication date. The information on the package insert could have been revised in November 2000 and the inserts not made public until after August 3, 2001. Accordingly, without evidence that the package insert was actually published before August 3, 2001, there is no evidence that the insert is "prior art" to the present application.

In addition, the M.V.I.-12 product is an intravenous infusion formulation. There is absolutely no teaching whatsoever in the package insert that the formulation would be suitable for oral administration. In fact, the package insert teaches away from oral administration by warning that the product is suitable for intravenous infusion only. It would be improper to use this formulation as an animal food additive.

With respect to the Lundberg document, this document concerns the use of lactate esters in many different applications, including pharmaceuticals and foodstuffs. There is no teaching whatsoever in Lundberg of the use of lactate esters in intravenous infusion formulations.

Accordingly, an artisan of ordinary skill in this art would not be motivated to combine the teachings of the Lundberg document with the teachings of the M.V.I.-12 package insert. It is quite possible that the use of the alkyl lactates described in Lundberg in the intravenous infusion formulation M.V.I.-12 would not only be illegal but dangerous. Accordingly, it is respectfully submitted that the combination of the M.V.I.-12 insert and the Lundberg document is improper and, in any event, would not provide the animal food additive of the present claims.

The rejection of claims 17, 37, 42 and 43 under 35 U.S.C. 103(a) as being unpatentable over M.V.I.-12 in view of Lundberg as applied to claims 1-9, 11-16, 18-27, 29, 31-36, 38-41, 44-45, 49-51, and further in view of the Multi-12 package insert, is respectfully traversed for the reasons set forth below.

As set forth above, there is no evidence that the M.V.I.-12 insert is actually prior art to the present application. Further, as set forth above, the combination of the M.V.I.-12 insert and the Lundberg document is clearly improper. In addition, it is respectfully submitted that the Examiner has not established that the Multi-12 package insert is prior art to the present patent application. The "date" for this document that the Examiner is referring to is not identified as a publication date or even as a date at all. It is just a string of numbers (i.e., 00-05-16) that is preceded by the identifier "package insert:". This is more likely to be a product designation number or insert code number than a date, especially since the numbers are not even written in the normal format for a date, where the year would be at the end of the series, not at the beginning. Further, the insert document is in "DRAFT" form (see pages 7 to 10 of insert as sent to applicants) and clearly indicates that the product has not yet been distributed or issued (see page 6 of insert as sent to applicants where the "Distributed by" line says "(To be determined)" and the "Issued" line says "Month/Year", without specifying a month or year). In view of the above, it is respectfully submitted that the Examiner has in no way established that the Multi-12 package insert was published prior to the filing date of the present application, which was August 3, 2001.

In addition, like the M.V.I.-12 product, the Multi-12 product is a intravenous infusion formulation that is not suitable for oral ingestion. Accordingly, this document is simply irrelevant to the animal food additive of the present claims.

The rejection of claims 10 and 30 under 35 U.S.C. 103(a) as being unpatentable over M.V.I.-12 in view of Lundberg as applied to claims 1-9, 11-27, 29, 31-45, 49-51, and further in view of The Merck Index, is respectfully traversed for the reasons set forth below.

The Merck Index extract cited by the Examiner teaches that ethoxyquin is a known antioxidant for use in feed and food. As acknowledged by the Examiner, none of the other cited references teach the use of ethoxyquin at all. It is the Examiner's position that it would have been obvious to one of ordinary skill in the art to substitute ethoxyquin for the BHT and/or BHA in the combined references. Initially, as discussed above, it is respectfully submitted that the Examiner has not established that the M.V.I.-12 package insert is prior art to the present patent application. In addition, it is respectfully submitted that it is not prima facie obvious to use an additive for feed or food in an intravenous infusion formulation. Without a teaching that such use is acceptable, such a substitution could cause death or severe injury to the animal to which the formulation is being administered. Accordingly, it is respectfully submitted that the teachings of the secondary references are not properly combinable with the teachings of the M.V.I.-12 package insert.

The rejection of claims 46-48 and 52-57 under 35 U.S.C. 103(a) as being unpatentable over M.V.I.-12 in view of Lundberg in further view of Multi-12 as applied to claims 1-9, 11-16, 18-27, 29, 31-36, 38-41, 44-45, 49-51, and further in view of Boussouira et al. (US 6,358,514) is respectfully traversed for the reasons set forth below.

It is the Examiner's position that Boussouira et al. teaches the use of retinol and retinyl propionate as combinable and interchangeable retinoids for use in bio-affecting compositions. It is respectfully submitted that, even if the Examiner's position was correct, the formulations of the Boussouira et al. patent are not relevant to the present invention or properly combinable with the formulations of the package inserts because they are topical formulations. Such formulations are not suitable for ingestion or intravenous infusion. Therefore, the Boussouira et al. patent is not relevant to the present invention and is not combinable with the teachings provided by the M.V.I.-12 and/or Multi-12 package inserts. Further, for all of the reasons discussed above, the Examiner has not even established that the package inserts are prior art to the present application. Accordingly, it is respectfully submitted that this rejection is clearly improper.

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In view of all of the above, it is respectfully submitted that the Examiner has not established a prima facie case of obviousness.

Reconsideration of the present application and a favorable action concerning claims 58-113 is respectfully requested.

Respectfully submitted,
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